K110590

510(k) Summary
for

APR 13 2012

Carl Zeiss Meditec AG
INTRABEAM® System Needle Applicator

per 21 CFR 807.92

1. SUBMITTER/510(K) HOLDER

Manufacturer: Carl Zeiss Meditec AG Carl-Zeiss-Strasse 22
D-73447 Oberkochen
Germany

Contact Person: Judith A. Brimacombe, MA
Director, Regulatory/Clinical Affairs
Carl Zeiss Meditec Inc.
5160 Hacienda Drive
Dublin, CA 94568
Phone: (925) 557-4616 FAX: (925) 557-4259

2. DEVICE NAME

Proprietary Name: Carl Zeiss INTRABEAM® System with Needle Applicator
Common/Usual Name: X-ray radiation therapy system
Classification Name: System, Therapeutic, X-ray, (21 CFR 892.5900) Product Code: IAD

3. PREDICATE DEVICES

- Photon Radiosurgery System PRS 400 System, K980526
- INTRABEAM® System with Balloon Applicator, most recently cleared in K090584

4. DEVICE DESCRIPTION

Physical Description

The proposed device is a modification of the INTRABEAM® System with Balloon Applicator, K090584, incorporating a Needle Applicator and guide shafts that are used to open a tract for the positioning of the applicator for irradiation of tumors.

The INTRABEAM® System that will be used with the new Needle Applicator accessory was most recently described in K090584. There are no modifications to the INTRABEAM® System hardware or software. The INTRABEAM® Core System

consists of the following components:

- PRS500 Control Console
- XRS4 X-ray source
- User terminal

Components of the Needle Applicator set are as follows:

1) Inner Sterile Packaging
2) 5 cm guide shaft
3) 6 cm guide shaft
4) Needle Applicator

How the Device Functions

The XRS 4 X-ray source generates X-rays according to the parameters set for the required treatment on the PRS500 Control Console. The Needle Applicator allows radiation treatment to be delivered directly to the target (e.g. an intracranial tumor).

Scientific Concepts that form the Basis for the Device

X-ray irradiation of tumors is a widely used treatment option in a variety of applications. The INTRABEAM® System delivers a controlled X-ray dose.

Significant Physical and Performance Characteristics of the Device, such as Device Design, Material Used, and Physical Properties

The physical design of the Needle Applicator consists of a polycarbonate case which fits over the probe of the XRS 4 X-ray source, a stainless steel shaft, and a polyetherimide tip for the Applicator. The guide shafts are stainless steel.

5. INTENDED USE

The Needle Applicator set (comprising the Needle Applicator and guide shafts) is intended for use in combination with the INTRABEAM® System to intraoperatively administer radiation to tissue including irradiation of intracranial tumors.

6. SUMMARY OF TECHNOLOGICAL CHARACTERISTICS COMPARED TO THE\PREDICATE DEVICE

Carl Zeiss Meditec AG claims substantial equivalence of the INTRABEAM® System with Needle Applicator to the cited predicate device based on the intended use, design, fundamental technology, and operation characteristics.

7. SUMMARY OF NON-CLINICAL PERFORMANCE TESTING AS BASIS FOR SUBSTANTIAL EQUIVALENCE

The testing summarized below supports the claim of substantial equivalence to the cited predicate by indicating that the Needle Applicator is a sterile device which performs as designed after sterilization and is safe for its intended use as is the predicate device.

Sterilization Validation

Sterilization validation of the Needle Applicator was performed in compliance with AAMI/ANSI/ISO 11137-1:2006, Sterilization of health care products – Radiation - Part 1: Requirements for development, validation, and routine control of a sterilization process for medical devices. Dose setting is performed in accordance with AAMI / ANSI/ISO 11137-2:2006, Sterilization of health care products - Radiation - Part 2: Establishing the sterilization dose, VDmax 25 method. Dosimetric release complies with AAMI/ANSI/ISO 11137-3:2006, Sterilization of health care products – Radiation – Part 3: Guidance on Dosimetric Aspects. The sterilization assurance level is 10^{-5}.

Performance Testing

The testing of the dosimetry of sterilized and aged INTRABEAM® Needle Applicator was performed to demonstrate that sterilization and accelerated aging exert no adverse effect on the INTRABEAM® Needle Applicator. Five samples were inspected visually before and after sterilization and accelerated aging. The functionality of Needle Applicators subjected to sterilization and accelerated aging equivalent to five years was tested by Carl Zeiss Meditec AG. All applicators passed the tests, were fully functional, and met the requirements of the engineering specifications.

Dosimetry testing of the PRS400 with the XRS probe (with sheath) compared to the INTRABEAM® System with Needle Applicator was conducted to demonstrate equivalence. The testing consists primarily of isotropy (radiation characteristics) and transfer functions (using a water phantom) using the same protocol used for past aging studies. The dose depth curves of the Needle Applicators tested matched those of the bare probe with sheath. The isotropy of the tested units met the criteria for passing the test.

Biocompatibility Testing Table 5-2. Biocompatibility Testing Performed on the Final Device Components

Material	Test	Comments	Result
Needle Applicator	Cytotoxicity EN ISO 10993-5	L 929 cell cultures, quantitative determination of cell proliferation	No relevant effects observed in comparison to controls
Guide shaft	Cytotoxicity EN ISO 10993-5	L 929 cell cultures, quantitative determination of cell proliferation	No relevant effects observed in comparison to controls
Needle Applicator	Chemical Analysis EN ISO 10993-18	GC-FID, quantification of organic and inorganic leachables	No relevant effects observed in comparison to controls

Based on the information and supporting documentation provided in the premarket notification, the Carl Zeiss INTRABEAM® Needle Applicator is substantially equivalent to the cited predicate devices. Testing demonstrates that the Carl Zeiss INTRABEAM® Needle Applicator fulfills prospectively defined design and performance specifications.

8. SUMMARY OF CLINICAL TESTING AS BASIS FOR SUBSTANTIAL EQUIVALENCE

No clinical testing was conducted to support this submission.

9. SUMMARY OF OTHER INFORMATION

No other information is provided.

10. CONCLUSIONS DRAWN FROM NON-CLINICAL AND CLINICAL TESTS

Based on the information and supporting documentation provided in the premarket notification, the Carl Zeiss INTRABEAM® System with Needle Applicator is substantially equivalent to the cited predicate device. Testing demonstrates that the Carl Zeiss INTRABEAM® with Needle Applicator fulfills prospectively defined design and performance specifications.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Carl Zeiss Meditec AG
Ms. Judith A. Brimacombe, MA
Director, Clinical/Regulatory Affairs
Carl Zeiss Meditec, Inc.
5160 Hacienda Drive
DUBLIN CA 94568

APR 13 2012

Re: K110590
Trade/Device Name: Carl Zeiss INTRABEAM® System with Needle Applicator
Regulation Number: 21 CFR 892.5900
Regulation Name: X-ray radiation therapy system
Regulatory Class: II
Product Code: JAD
Dated: March 2, 2012
Received: March 5, 2012

Dear Ms. Brimacombe:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Janine M. Morris
Acting Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K110590

Device Name: Carl Zeiss INTRABEAM® System with Needle Applicator

Indications for Use:

The Needle Applicator set (comprising the Needle Applicator and guide shaft) is indicated for use in combination with the INTRABEAM® System to intraoperatively administer radiation to tissue including irradiation of intracranial tumors.

Prescription Use _X_ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ___ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K110590